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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,377	06/28/2005	Yoshiaki Nabuchi	NABUCHI1	3839

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1612	

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09/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,377	NABUCHI ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 6-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 6-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 2, 3 and 6-14 are pending in the present application. The instant claims are rejected as indicated below.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1, 4 and 5 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.

4. The rejection of claims 2, 3 and 6-11 under 35 USC 112, first paragraph is withdrawn.

5. Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment, does not reasonably provide enablement for prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Briefly, the instant claims are drawn to compositions useful to prevent or treat osteoporosis or breast cancer.

The medical art teaches various treatment regimens for osteoporosis or breast cancer. However, the instant claims recite "preventing," which is deemed to be a "cure" since prevention of a disease is interpreted to mean that the disease will entirely cease to manifest after administration of the composition. Applicant has not demonstrated prevention or curing of osteoporosis or breast cancer in-vitro or even in a mouse/rat model in order to provide some reasonable nexus between the compounds instantly claimed and osteoporosis or breast cancer prevention.

While the Applicants might be enabled for treatment **in vitro**, the Applicants are not enabled for curing/preventing osteoporosis or breast cancer **in vitro** or **in vivo**. The high degree of unpredictability associated with the claimed method underscores the

need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide evidence that the instantly claimed compounds actually prevents or cures osteoporosis or breast cancer. Without such guidance in the specification and the lack of correlative working examples, the claims would require an undue experimentation without a predictable degree of success on the part of the skilled artisan.

Claim Objections

6. Claims 13 and 14; 7 and 8 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The recitation of the intended use does not limit the scope of the claimed composition.

Claim Rejections - 35 USC § 103

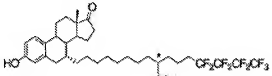
7. The rejection of claims 1, 4 and 5 under 35 USC 103(a) over Jo et al. (WO 0142186, see English translation US 6,737,417) is made moot by the cancellation of the instant claims.

8. The rejection of claims 2, 3 and 6-11 under 35 USC 103(a) over Jo et al. (WO 0142186, see English translation US 6,737,417) is maintained and claims 12-14 are rejected under 35 USC 103(a) over Jo et al. (WO 0142186, see English translation US 6,737,417).

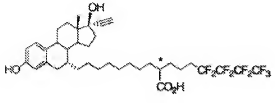
Applicant argues the rejection fails for the following reasons: (a) the structural differences between the claimed compounds and that of the prior art; (b) the advantageous effect of the claimed compounds and (c) it would not be predictive to modify the compounds of Jo et al. to arrive at the claimed compounds with a reasonable degree of success. Applicant's argument was considered but not persuasive for the following reasons.

First, the reference teaches a genus that encompasses the claimed compounds. The only difference between the prior art compounds exemplified and the claimed compounds are the substituents at the 17-position:

Claimed compounds:

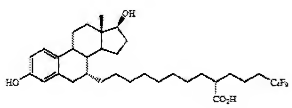


and

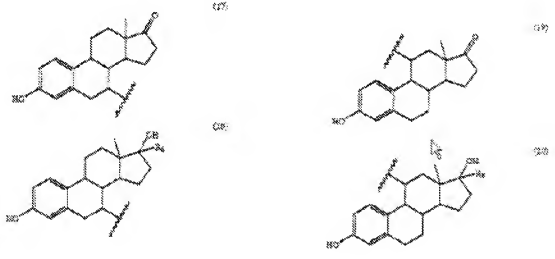


;

Exemplified Prior Art compound:



. However, as discussed in the previous Office Action, the reference teaches 17-substituents inclusive of the claimed compounds. For example:



(see definition of R_8 in the cited reference).

Applicant also argues the instant claims are optically active whereas the compounds of Jo et al. are diastereomer mixtures. However, applicant has not provided any evidence on record that the prior art compounds are diastereomer mixtures.

Secondly, applicant argues the advantageous effects of the claimed compounds. According to applicant, the claimed compounds exhibit different chemical properties

from the prior art compounds such as (a) a much higher AUC value; (b) potent pharmacological efficacy in oral administration; (c) potent anti-estrogenic activity and (d) excellent pharmacokinetic property. Thus, it is applicant's opinion that the claimed compounds show unexpected results.

To support the argument of unexpected results, applicant points to data in Tables 2 to 5 in the present specification. However the following are noted:

Table 2: The data shows compounds 2 and 5 have higher AUC values than control compounds 1 and 2. However, (a) compound 1 has a higher AUC value than control compound 1 but a lower or equal AUC value compared to control compound 2 and (b) compound 4 has a lower AUC value than control compounds 1 and 2.

Tables 4 and 5: shows data related to the claimed compounds but no comparison was made to the prior art compounds.

In essence, the examiner's position is that the data does not support the argument of unexpected results indicative of nonobviousness of the claims. Additionally, the reference teaches the compounds would have increased oral activity and, thus, differences in the AUC values would not be unexpected and/or unobvious.

Lastly, applicant argues the rejection fails because it would not be predictive to modify the compounds of Jo et al. to arrive at the claimed compounds with a reasonable degree of success. However, what the skilled artisan would be doing is making additional species of the genus taught by Jo et al. Thus, based on the teachings of the cited reference he would have the reasonable expectation that any species of the genus of Jo would have similar properties as taught by the reference and, thus, have

increased activity after oral administration (see Abstract; col. 2, line 66 - col. 3, line 13 of the cited reference).

For these reasons and those given in the previous Office Action, the rejection of claims 2, 3 and 6-11 under 35 USC 103(a) over Jo et al. (WO 0142186, see English translation US 6,737,417) is maintained and claims 12-14 are rejected under 35 USC 103(a) over Jo et al. (WO 0142186, see English translation US 6,737,417).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612